

## Participant Information Sheet

### SEQUENCE Digital: Sexual health equity through evidence-based online clinical care – Pre-Trial Qualitative Studies (Study A)

#### Introduction

More and more sexual healthcare is moving online and the Covid-19 pandemic is making this change happen even quicker than before. In the future, it is possible that people could do everything online that they would normally do at a face-to-face appointment in a physical sexual health clinic. Our study aims to understand how we can deliver online sexual healthcare to meet the needs and requirements of a diverse range of people. We are especially interested in the views of people who have never used or who have had difficult experiences of using online sexual healthcare in the past.

We are looking to interview people who are:

- 16 years of age or older **and**
- Live in the UK **and**
  - Are sexually active (i.e., have had sexual intercourse within the previous 12 months).
  - Do not use or have tried but not managed to use postal STI (sexually transmitted infection) self-sampling services.
  - Have access to the Internet and a telephone.
  - Are able to understand what the study is asking from them and to consent to this.
  - Are able to read and speak English well enough to participate in an interview.

The study is being carried out as part of the SEQUENCE Digital (*'Sexual health equity through evidence-based online clinical care: Improving sexual healthcare for all, in a digital NHS'*) project, which aims to improve access to online sexual health services and develop an online clinic to help people and their partners test for STIs and receive STI care and treatment. The SEQUENCE Digital project is conducted by a team of researchers at Glasgow Caledonian University (GCU) and University College London (UCL). Central and North West London (CNWL) NHS Foundation Trust is the project Sponsor, in collaboration with researchers at GCU and UCL. GCU is providing indemnity for the SEQUENCE Digital project. The team at GCU is leading the work for this specific study. CNWL NHS Foundation Trust is the data controller and Professor Claudia Estcourt, the Chief Investigator, is the data custodian.

Before you decide if you want to take part, it is important for you to understand what participation in this study would involve. Please take some time to read the following information carefully and discuss it with others if you wish. Please contact Jennifer MacDonald ([XXXXXX@nhs.net](mailto:XXXXXX@nhs.net)) if you would like more information.

#### Why is the study important?

This study is important as it allows people who have never used or who have had difficult experiences of using online sexual health services the opportunity to express their views on six different activities that people might undertake when using online sexual health services. We will use what we learn from this study to improve our eSexual Health Clinic (an innovative online sexual health clinic, which showed

promise in small pilot studies). Further down the line we will test the improved eSexual Health Clinic in a clinic trial. If successful, this could change sexual healthcare in the future.

### **What will I be asked to do if I take part?**

You will be asked to share some information about you, your personal circumstances (e.g. age, gender, sexual orientation, ethnicity, any disability, highest qualification, occupation, postcode, county of birth, first language, religion/faith, socioeconomic status, social support), and your Internet access and use during an initial call about the study.

Within an interview, you will be asked what you know, if anything, about online sexual health services. We will also explore your views on six different activities that people might take part in when using online sexual health services. We will ask you to think about the main factors or considerations (positive and negative) that could influence your decision on whether or not to do each activity. We will discuss the following activities: searching for sexual health information online; getting sexual health support and advice online; ordering a postal STI self-sampling kit online; doing the tests and sending them to a lab to be tested; getting STI test results via a secure website; and getting STI treatment via a secure online assessment. The researcher will explain each activity to you, so do not worry if you've never heard of or are unsure about any the activities before the interview. The researcher may also show you some images and examples to help your understanding.

The interview should last around 60 minutes. It will most likely take place remotely, either by phone call, audio/video call using an encrypted messaging service (e.g., WhatsApp), or an audio/video conferencing service (e.g., Microsoft Teams, Zoom). The interview may also take place in person, but only if you and the researcher decide that this is the best option and if local COVID-19 restrictions allow. The interview will take place at a time that is convenient to you and the researcher.

Just before the interview, we will ask if you have any questions about the study. We will read through the consent form (you should have a copy) and make sure you are okay to do the interview. This is known as 'consent'. If you take part in a face-to-face interview, you will be asked to sign two copies of a paper copy consent form. One copy will be provided to you and the other copy will be stored in a secure location at GCU. If you take part in a remote interview, we will record your verbal consent and store this recording on secure GCU computers under password protection. If you agree to take part in the study, then we'll start the interview recording. The interview recording will also be uploaded to a secure GCU computer, stored away from your verbal consent recording.

At the end of the interview, you will be offered a £30 gift voucher as a token of 'thanks' for your time. If you accept, a voucher code can either be sent to you via email or encrypted messaging service (e.g. WhatsApp) or a paper voucher can be sent to you by post. We will also share information about some mental and sexual health support services. This information will be sent regardless of whether any difficult issues arise in the interview.

### **Do I have to take part?**

No. Participation is voluntary and it is up to you to decide if you would like to take part in the study. If you do take part, you can take a break or stop the interview at any point. You can also ask for your interview and other personal information to be deleted at any time up until the point that no further

data is being collected (approximately December 2021). You do not need to give a reason for this and it will not affect your access to NHS services or treatment, now or in the future.

### **What are the possible risks of taking part?**

We think that it is unlikely that you would come to any harm through taking part in the study. In the interview, we may touch upon any previous experiences you have of STI testing in a physical sexual health clinic. This could potentially bring up unpleasant memories for you. The researcher conducting the interview is experienced in talking with people about these topics and will support you during the interview, if you do become upset. You do not have to answer any questions you do not wish to, and you can take a break or stop the interview at any time. You will also be provided with a document that details mental and sexual health support services at the end of the interview. There is a risk that the researcher may have to break your confidentiality to tell someone about what was discussed in the interview, if it is necessary to protect your or another person's safety. The researcher will discuss this with you first, whenever possible.

### **What are the possible benefits of taking part?**

We can't promise that you will benefit directly from taking part. However, you may benefit indirectly by having an opportunity to express your views on online sexual health services in the UK, particularly those services that help people and their partners to test for STIs and receive STI care and treatment, and by suggesting improvements for future online sexual health service provision.

### **What happens when the study stops?**

After the interview ends, the audio recording will be turned into a written document by a professional transcriber who has signed a confidentiality agreement. The audio recording and the transcript will be pseudonymised; this means they will be identified using a code number and not your name or any other personally identifiable information about you.

Once your transcript is returned from the professional transcription company and checked for accuracy, we will destroy your interview recording. Your contact details, which will be held separately to the rest of your information, on secure NHS computers and within the encrypted @NHS.net email service, will be destroyed at the end of the study (anticipated April 2022). We will keep your verbal consent recording, transcript, demographic information, and information on Internet access and use on secure GCU computers under password protection for a minimum of 10 years. Only members of the research team will have access to this data. Other researchers employed by the universities affiliated with the SEQUENCE Digital project and students studying on courses at these universities may request to access this data through the Chief Investigator, who is responsible for how the study is conducted. Access to this anonymous data will only be permitted if you have explicitly consented and if it is appropriate for their research.

Interview transcripts will be transferred between the research team via email for analysis and cross-checking purposes. We will analyse your transcript along with those of other participants and share our results in a number of ways. The findings may be presented at different events to let people know what we found in the study. The findings will also be written up and submitted for publication in academic journals and presented at scientific conferences. We will not include any identifiable information about you in our presentation of these findings. If we use a quote of something you said

during your interview, we will make sure it does not describe specific incidents or situations where you or other people you have mentioned could be identified. In addition, we will only use pseudonyms and broad terms to describe participants (e.g., man who has sex with men, aged 30-40 years).

The findings will be used to inform the development and refinement of online sexual health services. Copies of our publications and summaries of our findings written especially for patients and members of the public will be available on our study website ([www.sequencedigital.org.uk](http://www.sequencedigital.org.uk)). They can also be requested from Jennifer MacDonald ([XXXXXX@nhs.net](mailto:XXXXXX@nhs.net)).

### **What if there's a problem?**

If you are concerned about your participation in the study and would like to speak with someone else within the study team, please contact Paul Flowers ([paul.flowers@strath.ac.uk](mailto:paul.flowers@strath.ac.uk)). You may also contact the Sponsor, CNWL NHS Foundation Trust ([sponsor.noclor@nhs.net](mailto:sponsor.noclor@nhs.net)), and the Patient Feedback and Complaints Service for CNWL NHS Foundation Trust (email: [feedback.cnwl@nhs.net](mailto:feedback.cnwl@nhs.net) and telephone: 0300 013 4799).

### **How will we use information about you?**

We will need to use information from you for this study. This information will include:

- your name (you can provide your first name only or your first and last names).
- your phone number and/or email address.
- your clinic number.
- if you live in the UK and are sexually active.
- your age, gender, sexual orientation, ethnicity, any disability, highest qualification, occupation, postcode, county of birth, first language, religion/faith, socioeconomic status, social support.
- your Internet access and use, including current use of STI self-sampling services.

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead, linked to your clinic number in a study log stored on GCU computers that require password access. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

### **What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason. You can choose to have your data removed from the study up until the point we stop collecting new data (around December 2021). After that, we will not be able to remove your data and we will keep the information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

### **Where can you find out more about how your information is used?**

You can find out more about how we use your information:

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/).

- our leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch).
- by asking the researcher, Jennifer MacDonald ([XXXXX@nhs.net](mailto:XXXXX@nhs.net)).
- by sending an email to the Sponsor's Data Protection Officer ([cnwl.dpo@nhs.net](mailto:cnwl.dpo@nhs.net)).
- by ringing us on [number TBC](#).

### Who has reviewed the study?

All studies involving human participants are reviewed by an ethics committee. The role of the ethics committee is to protect the safety, rights, wellbeing, and dignity of study participants. This study (IRAS number 299331) was reviewed by the East of England - Cambridge South Research Ethics Committee and given ethical approval on 29/06/21 under the following approval code: 21/EE/0148.

### How do I make contact with the study team?

If you have any questions about the study, please email Jennifer MacDonald at: [XXXXX@nhs.net](mailto:XXXXX@nhs.net)

### What happens next?

The researcher will contact you to ask if you are still interested in taking part in the study and answer any questions about the study. They will check that you are eligible to participate and if you are, they will ask you some basic details about you, your personal circumstances, and your Internet access and use. We will use this information to decide whether we can interview you. **There is a chance that you might not be selected** as we are looking to speak to a diverse range of people in order to design online sexual health services that are as inclusive and accessible as possible. If you are selected and agree to take part, the researcher will arrange a mutually convenient time to do the interview.

Thank you for taking the time to read this information.



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